

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

MIETTINEN et al.

Attorney Dkt. No.: 019075-00062

Application No.: Not yet assigned (Continuation of USSN 10/289,431)

Filed: Herewith

For: A SUBSTANCE FOR LOWERING HIGH CHOLESTEROL LEVEL IN SERUM AND METHODS FOR PREPARING AND USING THE SAME

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

October 6, 2003

Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the information items listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each item is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the items be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

- ☒ 1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date, OR (b) before the mailing date of a first Office Action on the merits in the present application, OR (c) accompanies a Request for Continued Examination. No certification or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
- ☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).
- ☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).
- ☐ c. A check in the amount of \$180.00 in payment of the fee under 37 CFR §1.17(p). Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300 as needed to ensure consideration of the

disclosed information.

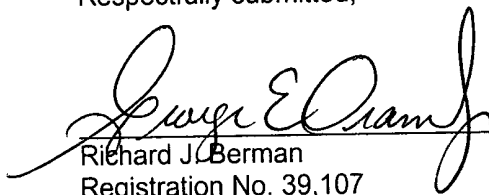
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Applicant(s) hereby petition(s) that the Information Disclosure Statement be considered. Attached is our check in the amount of \$180.00 in payment of the petition fee under 37 CFR §1.17(i)(1). Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300 as needed to ensure consideration of the disclosed information.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).

- ☒ 4. The reference(s) was/were cited by or submitted to the Office in parent application No. 10/289,431, filed November 7, 2002, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these references are not attached. 37 CFR § 1.98(d).

Respectfully submitted,


Richard J. Berman
Registration No. 39,107
27931


Customer No. 004372
ARENT FOX KINTNER PLOTKIN & KAHN, PLLC
1050 Connecticut Avenue, N.W.,
Suite 400
Washington, D.C. 20036-5339
Tel: (202) 857-6000
Fax: (202) 638-4810
RJB/ccd

[illegible][illegible]

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.1⁶ if possible. ⁷Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this Box 4498/PTO
Rev. 10/95U.S. Department of Commerce
Patent and Trademark Office

Complete if Known

**LIST OF PRIOR ART CITED BY
APPLICANT**

(use as many sheets as necessary)

Application Number

Div. of 09/713,030

Filing Date

First Named Inventor

Tatu Miettinen

Group Art Unit

Examiner Name

Attorney Docket Number

019075-00058

Sheet

2

of

15

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T ²
		European Journal of Clinical Investigation, Vol. 10, pp. 27-35, (1980), T. Miettinen "Phytosterolaemia, Xanthomatosis and Premature Atherosclerotic Arterial Disease: A Case with High Plant Sterol Absorption, Impaired Sterol Elimination and Low Cholesterol Synthesis"	
		Scand. J. Gastroenterol. Vol. 21, pp. 967-972, (1986), K. Nidkila, et al. "Serum Cholesterol Precursors, Cholesterol, and Plant Sterols in Primary Biliary Cirrhosis"	
		Z. Klin. Chem. Biochem., Vol. 9, pp. 47-52, (1971), T. Miettinen, et al. "Bile Salts, Sterols, Sterol Esters, Glycides and Fatty Acids in Micellar and Oil Phases of Intestinal Contents During Fat Digestion in Man"	
		Journal of Lipid Research, Vol. 20, pp. 648-653, (1979), A. Hassan, et al. "Intestinal Absorption and Lymphatic Transport of Cholesterol and β -Sitosterol in the Rat"	
		Journal of Organic Chemistry, Vol. 25, pp. 1209-1219, (1960), A. Kuksis, et al. "Preparation and Certain Physical Properties of Some Plant Steryl Esters"	
		Synthetic Communications, Vol. 16, pp. 1423-1430, (1986), M. Sarcja, et al. "A Convenient Method of Esterification of Fatty Acids, Preparation of Alkyl Esters, Sterol Esters, Wax Esters and Triacylglycerols"	
		Lipids, Vol. 12, pp. 242-244, (1977), A. Prabhudesai "A Simple Method for the Preparation of Cholesterol Esters"	
		Chemistry and Physics of Lipids, Vol. 15, pp. 216-221, (1975), B. Lentz, et al. "A Simple Method for the Synthesis of Cholesterol Esters in High Yield"	
		Organic Preparations and Procedures, Vol. 1(2), pp. 107-109, (1969), R. Augustine, et al. "The Palladium Catalyzed Hydrogenation of Cholesterol"	
		Journal of American Oil Chemists' Society, Vol. 55, pp. 796-805, (1978), B. Sreenivasan "Interestification of Fats"	
		Journal of American Oil Chemists' Society, Vol. 60, pp. 315-318, (1983), Y. Lo, et al. "Physical and Chemical Properties of Randomly Interestified Blends of Soybean Oil and Tallow for Use as Margarine Oils"	

Examiner
SignatureDate
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this Box: ☐

1449B/PTO Rev. 10/95		U.S. Department of Commerce Patent and Trademark Office		Complete if Known	
LIST OF PRIOR ART CITED BY APPLICANT (use as many sheets as necessary)		Application Number		div. of 09/713,030	
		Filing Date			
		First Named Inventor		Tatu Meitinen	
		Group Art Unit			
		Examiner Name			
Sheet	3	of	15	Attorney Docket Number 019075-00058	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T ¹
		Circulation, Vol. 7, pp. 702-706, (May 1953), O. Potlak "Reduction of Blood Cholesterol in Man"	
		Proc. Soc. Exp. Biol. Med., Vol. 78, pp. 143-147, (1951), D. Peterson "Effect of Soybean Sterols in the Diet on Plasma and Liver Cholesterol in Chicks"	
		Circulation, Vol. 7, pp. 696-701, (May 1953), O. Potlak "Successful Prevention of Experimental Hypercholesterolemia and Cholesterol Atherosclerosis in the Rabbit"	
		Circulation, Vol. 17, pp. 890-899, (May 1958), J. Farquhar, et al. "Response of Serum Lipids and Lipoproteins of Man to Beta-Sitosterol and Safflower Oil"	
		Journal of Lipid Research, Vol. 10, pp. 304-315, (1969), S. Grundy, et al. "The interaction of Cholesterol Absorption and Cholesterol Synthesis in Man"	
		Deutsche Medizinische Wochenschrift, Vol. 101, pp. 1308-1311, (September 1976), P. Oster, et al. "Sitosterin bei familiärer Hyperlipoproteinämie Typ II"	
		Atherosclerosis, Vol. 28, pp. 325-338, (1977), A. Lees, et al. "Plant Sterols as Cholesterol-Lowering Agents: Clinical Trials in Patients with Hypercholesterolemia and Studies of Sterol Balance"	
		Münch. Medizinische Wochenschrift, Vol. 120, pp. 1575-1578, (1969), W. Schwartzkopff, et al. "Dosiswirksamkeit von μ -Sitosterin bei Hypercholesterinämien der Typen Ia und Ib"	
		The American Journal of Clinical Nutrition, Vol. 43, pp. 92-97, (January 1986), R. Tilvis, et al. "Serum Plant Sterols and Their Relation to Cholesterol Absorption"	
		American Journal of Epidemiology, Vol. 131, No. 1, pp. 20-31, (1990), T. Meitinen, et al. "Serum Plant Sterols and Cholesterol Precursors Reflect Cholesterol Absorption and Synthesis in Volunteers of a Randomly Selected Male Population"	
		Scand. Journal Clin. Lab. Invest., Vol. 48, pp. 715-722, (1988), M. Färkkilä, et al. "Regulation of Plasma Plant Sterol Levels in Patients with Gut Resections"	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this Box: ☐

1449B/PTO Rev. 10/85		U.S. Department of Commerce Patent and Trademark Office		Complete if Known	
LIST OF PRIOR ART CITED BY APPLICANT (use as many sheets as necessary)				Application Number	div. of 09/713,030
				Filing Date	
				First Named Inventor	Tatu Miettinen
				Group Art Unit	
				Examiner Name	
Sheet	4	of	15	Attorney Docket Number	019075-00058

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T ²
		Chemical Abstracts, Vol. 115, No. 1, (1991), T. Heinemann, et al. "Mechanisms of Action of Plant Sterols on Inhibition of Cholesterol Absorption: Comparison of Sitosterol and Sitostanol"	
		Chemical Abstracts, Vol. 112, No. 7, (1990), I. Ikeda, et al. "Effects of Sitosterol and Sitostanol and Micellar Solubility of Cholesterol"	
		Chemical Abstracts, Vol. 112, No. 7, (1990), T. Heinemann, et al. "Comparison of Sitosterol and Sitostanol on Inhibition of Intestinal Cholesterol Absorption"	
		Chemical Abstracts, Vol. 95, No. 13, (1991), I. Ikeda, et al. "Antihypercholesterolemic Activity of β -Sitostanol in Rabbits"	
		Chemical Abstracts, Vol. 88, No. 3, (1978), M. Sugano, et al. "A Comparison of Hypocholesterolemic Activity of β -Sitosterol and β -Sitostanol in Rats"	
		Chemical Abstracts, Vol. 71, No. 1, (1969), T. Tsuchiya "Sitosterol Fatty Acid Ester"	
		International Search Report, dated 12/11/91.	
		International Preliminary Exam Report, dated 08/04/93.	
		Copy of Written Opinion from International Preliminary Exam Authority, dated 04/14/93.	

Examiner Signature	Date Considered	
--------------------	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this Box ☐1449B/PTO
Rev. 10/95U.S. Department of Commerce
Patent and Trademark OfficeComplete if: ☐**LIST OF PRIOR ART CITED BY
APPLICANT**

(use as many sheets as necessary)

Application Number

Div. of 09/713,030

Filing Date

First Named Inventor

Tatu Miettinen

Group Art Unit

Examiner Name

Attorney Docket Number

019075-00058

Sheet

5

of

15

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T
		Lipoprotein Metabolism, pp. 112-118, (1976), (Ed. H. Greten Berlin, Heidelberg, New York: Springer-Verlag), S. Grundy, et al. "Effects of Low Dose Phytosterols on Cholesterol Absorption in Man"	
		Atherosclerosis, Vol. 23, pp. 239-248, (1978), B. Kuchodkar, et al. "Effects of Plant Sterols on Cholesterol Metabolism in Man"	
		Journal of Lipid Research, Vol. 29, pp. 1573-1582, (1988), I. Ikeda, et al. "Inhibition of Cholesterol Absorption in Rats by Plant Sterols"	
		Journal of Lipid Research, Vol. 29, pp. 1583-1591, (1988), I. Ikeda, et al. "Discrimination between Cholesterol and Sitosterol for Absorption in Rats"	
		J. Nutr. Sci. Vitaminol, Vol. 35, pp. 361-369, (1989), I. Ikeda, et al. "Effects of Sitosterol and Sitostanol on micellar Solubility of Cholesterol"	
		Atherosclerosis, Vol. 30, pp. 227-237, (1978), I. Ikeda, et al. "Comparison of Absorption and metabolism of β -Sitosterol and β -Sitostanol in Rats"	
		J. Nutr., Vol. 107, pp. 2011-2019, (1977), M. Sugano, et al. "A Comparison of Hypocholesteremic Activity of β -Sitosterol and β -Sitostanol in Rats"	
		Atherosclerosis, Vol. 61, pp. 219-223, (1986), T. Heinemann, et al. "Effect of Low-Dose Sitostanol on Serum Cholesterol in Patients with Hypercholesterolemia"	
		Lipoprotein Metabolism, pp. 119-124, (1976), (Ed. H. Greten, Berlin, Heidelberg, New York: Springer-Verlag), R. Lees, et al. "Effects of Sitostanol Therapy on Plasma Lipid and Lipoprotein Concentrations"	
		J. Nutr., Vol. 107, pp. 1139-1148, (1977), F. Mattson, et al. "Effect of Plant Sterol Esters on the Absorption of Dietary Cholesterol"	
		Agents Actions (Suppl.), Vol. 26, pp. 117-122, (1988), T. Heinemann, et al. "Comparison of Sitosterol and Sitostanol on Inhibition of Intestinal Cholesterol Absorption"	

Examiner Signature	Date Considered
--------------------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this Box ☐4498/PTO
Rev. 10/95U.S. Department of Commerce
Patent and Trademark Office

Complete if Known

**LIST OF PRIOR ART CITED BY
APPLICANT**

(use as many sheets as necessary)

Application Number

Div. of 09/713,030

Filing Date

First Named Inventor

Tatu Miettinen

Group Art Unit

Examiner Name

Attorney Docket Number

019075-00058

Sheet

6

of

15

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS


Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T ²
		Journal of Lipid Research, Vol. 18, pp. 203-210, (1977), R. Jandacek, et al. "Effect of an Aqueous Phase on the Solubility of Cholesterol in an Oil Phase"	
		Life Sciences, Vol. 57, No. 1, pp. 195-208, W.H. Ling, et al. "Dietary Phytosterols: A Review of Metabolism, Benefits and Side Effects"	
		Bile Acids and Cholesterol in Health and Disease, Falk Symposium 33, pp. 183-187, L.A. Miettinen, et al. "Non-Cholesterol Sterols and Bile Acid Production in Hypercholesterolemic Patients with Bile Bypass"	
		Atherosclerosis, Vol. 105, pp. 217-228, (1994), L.A. Miettinen, et al. "Dietary Sitostanol Related to Absorption, Synthesis and Serum Level of Cholesterol in Different Apolipoprotein E Phenotypes"	
		The New England Journal of Medicine, Vol. 333, pp. 1308-1312, (1995), T.A. Miettinen, et al. "Reduction of Serum Cholesterol with Sitostanol-Ester Margarine in a Mildly Hypercholesterolemic Population"	
		Pharmac. Ther., Vol. 31, pp. 177-208, (1985) O.J. Pollak "Effect of Plant Sterols on Serum Lipids and Atherosclerosis"	
		Atherosclerosis, Vol. 24, pp. 301-309 (1978), M. Sugano, et al. "Lipid-Lowering Activity of Phytosterols in Rats"	
		Clinica Chimica Acta, Vol. 205, pp. 97-107, (1992), H.T. Vanhanen, et al. "Effects of Unsaturated and Saturated Dietary Plant Sterols on their Serum Contents"	
		Journal of Lipid Research, Vol. 24, pp. 1535-1544, (1993), H.T. Vanhanen, et al. "Serum Cholesterol, Cholesterol Precursors, and Plant Sterols in Hypercholesterolemic Subjects with Different apoE Phenotypes During Dietary Sitostanol Ester Treatment"	
		Clinical Science, Vol. 87, pp. 61-67, (1994), H.T. Vanhanen et al. "Serum Levels, Absorption Efficiency, Faecal Elimination and Synthesis of Cholesterol During Increasing Doses of Dietary Sitostanol Esters in Hypercholesterolemic Subjects"	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this Box 

14498/PTO Rev. 10/95		U.S. Department of Commerce Patent and Trademark Office		Complete if Known	
LIST OF PRIOR ART CITED BY APPLICANT (use as many sheets as necessary)				Application Number	Div. of 09/713,030
				Filing Date	
				First Named Inventor	Tatu Meitinen
				Group Art Unit	
				Examiner Name	
Sheet 7 of 15			Attorney Docket Number	019075-00058	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T ¹
		European Journal of Clinical Pharmacology, Vol. 40 (Suppl.), pp. 559-563, (1991), T. Heinemann, et al. "Mechanisms of Action of Plant Sterols on Inhibition of Cholesterol Absorption"	
		The American Journal of Clinical Nutrition, Vol. 35, pp. 697-700, (1982), F. Mattson, et al. "Optimizing the Effect of Plant Sterols on Cholesterol Absorption in Man"	
		J. Clin. Invest., Vol. 80, pp. 578-581, (August 1987), Y. Kesäniemi, et al. "Intestinal Cholesterol Absorption Efficiency in Man is Related to Apolipoprotein E Phenotype"	
		Annals of Clinical Research, Vol. 20, pp. 28-31, (1988), Y. Kesäniemi, et al. "Metabolic Epidemiology of Plasma Cholesterol"	
		Journal of Lipid Research, Vol. 27, pp. 227-235, (1986), C. Ehnholm, et al. "Apolipoprotein E Polymorphism in the Finnish Population: Gene Frequencies and Relation to Lipoprotein Concentrations"	
		The Lancet, Vol. 2, pp. 1281, (November 1988), T. Meitinen, et al. "Serum Cholesterol Response to Dietary Cholesterol and Apolipoprotein E Phenotype"	
		N.Y. Academy of Sciences, Vol. 2, pp. 129-134, (1955), G. Gould "Absorbability of Beta-Sitosterol"	
		Metabolism, Vol. 18, pp. 652-662, (1969), G. Gould, et al. "Absorbability of Beta-Sitosterol in Humans"	
		The Journal of Clinical Investigation, Vol. 49, pp. 952-967, (1970), G. Salen, et al. "Metabolism of β -Sitosterol in Man"	
		Journal of Lipid Research, Vol. 26, pp. 203-209, (1985), G. Salen, et al. "Increased Plasma Cholesterol and 5 α -Saturated Plant Sterol Derivatives in Subjects with Sitosterolemia and Xanthomatosis"	
		Journal of Lipid Research, Vol. 30, pp. 1319-1330, (1989), G. Salen, et al. "Increased Sitosterol Absorption, Decreased Removal, and Expanded Body Pools Compensate for Reduced Cholesterol Synthesis in Sitosterolemia with Xanthomatosis"	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Please type a plus sign (+) inside this Box ☐

4458/PTO Rev. 10/85		U.S. Department of Commerce Patent and Trademark Office		Complete if Known	
LIST OF PRIOR ART CITED BY APPLICANT (use as many sheets as necessary)				Application Number	55/ 09/713,030
				Filing Date	
				First Named Inventor	Tatu Miettinen
				Group Art Unit	
				Examiner Name	
Sheet	8	of	15	Attorney Docket Number	9975-00058

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T
		Journal of American Oil Chemists' Society, Vol. 54, pp. 47-50, (1977), D. Chobanov, et al. "Alterations in Glycide Composition During Interestification of Mixtures of Sunflower Oil with Lard and Tallow"	
		"Thermodynamic and Molecular Determinants of Sterol Solubilities in Bile Salt Micelles", Vol. 28, pp. 1144-1155, (1987), M. Armstrong, et al.	
		Pediatric Pharmacology and Therapeutics, Vol. 122, No. 2, pp. 292-296, (1993), M. Becker, MD., et al. "Treatment of Severe Familial Hypercholesterolemia in Childhood with Simvastatin and Simvastatin"	
		Papers and Notes on methodology, Vol. 32, pp. 1861-1867, (1991), J. Czabayko, et al. "A Simplified Micro-Method for Quantification of Fecal Excretion of Neutral and Acidic Sterols for Outpatient Studies in Humans"	
		Steroids, Vol. 40, No. 2, pp. 233-243, (1982), S. Dayal, et al. "Identification of 5 α -Stanois in Patients with Simvastatin and Xanthomatosis: Stereochemistry of the Protonolysis of Steroidal Organoboranes"	
		J. Sci. Food Agric., Vol. 71, pp. 383-391, (1996), P. Dutta, et al. "Saturated Sterols (Stanois) in Unhydrogenated and Hydrogenated Edible Vegetable Oils and in Cereal Lipids"	
		Treatment of Severe Dyslipoproteinemia in the Prevention of Coronary Heart Disease, Vol. 4, pp. 57-59, (1993) H. Gylling, et al. "Serum Cholesterol Lowering by Dietary Simvastatin is Associated with Reduced Absorption and Synthesis of Cholesterol and Decreased Transport of LDL Apoprotein B in Men with Type II Diabetes"	
		Diabetologia, Vol. 37, pp. 773-780, (1994), H. Gylling et al. "Serum Cholesterol and Cholesterol and Lipoprotein Metabolism in Hypercholesterolemic NIDDM Patients Before and During Simvastatin Ester-Margarine Treatment"	
		Journal of Lipid Research, Vol. 38, pp. 1807-1812, (1995), H. Gylling et al. "Simvastatin Ester Margarine in Dietary Treatment of Children with Familial Hypercholesterolemia"	
		European Journal of Clinical Investigation, Vol. 23, pp. 327-331, T. Heinemann, et al. "Comparison of Intestinal Absorption of Cholesterol with Different Plant Sterols in Man"	
		J. Nutr. Sci. Vitaminol, Vol. 27, pp. 243, 252, (1981), I. Ikeda et al. "Antihypercholesterolemic Activity of β -Sitostanol in Rabbits"	

Examiner Signature	Date Considered
--------------------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*Unique citation designation number. *Applicant is to place a check mark here if English language Translation is attached.

SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

ATTY. DCKET N.

SERIAL N.

619075-00058

Div of 09/713,030

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT

MIETTENEN et al.

FILING DATE

GROUP

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AM	POLLAK, O.J., "Effect of Plant Sterols on Serum Lipids and Atherosclerosis", Pharmac. Ther. Vol. 31, pp. 177 to 208, 1985.
AN	JIMÉNEZ DE BLAS, et al., "Determination of Sterols by Capillary Column Gas Chromatography. Differentiation Among Different Types of Olive Oil: Virgin, Refined, and Solvent-Extracted" JAACS, Vol. 73, no. 12, pp. 1685-1689 (1996).
AO	DEUEL, JR., "The Lipids - Their Chemistry and Biochemistry", Vol. I: Chemistry, 1951, Interscience Publishers, Inc., N.Y.
AP	SCHUHMANN et al., "METHODS FOR QUALITATIVE AND QUANTITATIVE DETERMINATION OF PHYTOSTEROLS IN VEGETABLE OILS BY LC-GC OFF-LINE", Mitt. Gebiete Lebensm. Hyg. vol. 87, pp. 708-715 (1996).

EXAMINER

DATE CONSIDERED

*EXAMINER:

Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 019075-00058	SERIAL NO. Div. of 09/713,030
LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT MIETTINEN, et al.	
		FILING DATE Herewith	GROUP unknown

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	BA	KOBAYASHI et al., Translation of JP 57-206336 (1982).
	BB	PETERSON et al., "Depression of plasma cholesterol in human subjects consuming butter containing soy sterols", Fed. Proc., 1956, Vol. 15, Page 569.
	BC	VANHANEN et al., "Effects of unsaturated and saturated dietary plant sterols on their serum contents", Clinica Chimica Acta, Vol. 205, 1992, Pages 97-107.
	BD	VANHANEN et al., "Serum cholesterol, cholesterol precursors, and plant sterols in hypercholesterolemic subjects with different apoE phenotypes during dietary sitostanol ester treatment", Journal of Lipid Research, Vol. 34, 1993, Pages 1535-1544.
	BE	Preliminary Opinion prepared by the Opposition Division in European Patent No. 0 594,612 (granted on Application No. 91908435.0), December 17, 1999, pages 1-7.
	BF	Main Request - May 4, 1999 filed in the European Patent Office in European Patent No. 0 594 612 (granted on Application No. 91908435.0)
	BG	Summons to Attend Oral Proceedings European Patent No. 0 594 612 (granted on Application No. 91908435.0), March 21, 2001.
	BH	MATTSON et al., "Effect of an aqueous phase on the solubility of cholesterol in an oil phase", J. of Lipid Research, Vol. 18, pages 203-210, 1977.
	BI	Studies with stanol fatty acid esters, 5 pages
	BJ	WESTSTRATE et al., "Plant sterol-enriched margarines and reduction of plasma total-and LDL-cholesterol concentrations in normocholesterolaemic and mildly hypercholesterolaemic subjects", European J. Clin. Nutr., Vol. 52, pages 334-343, 1998.
	BK	Opposed patent as filed in Finnish; Title: A substance for lowering high cholesterol level in serum and a method for preparing the same"; Inventors: MIETTINEN et al.
	BL	Norm NEN 3428
	BM	

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 019075-00058	SERIAL NO. Div of 09/713,030
LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT MIETTINEN, et al.	
		FILING DATE Herewith	GROUP unknown

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA	5,244,887	09/1993	STRAUB			
	AB	4,160,850	07/1979	HALLSTROM et al.			
	AC	1,413,102	11/1975	JANDACEK			
	AD	3,852,311	12/1974	NICHOLAS et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION		
							YES	NO	PART.
	AE	WO 98/06405	02/1998	PCT					
	AF	WO 96/38047	12/1996	PCT					
	AG	567,202	12/1958	CANADA					
	AH	WO 92/19640	11/1992	PCT					
	AI	967616	09/1996	ZA					
	AJ	WO 97/42830	11/1997	PCT					
	AK								

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AL	Opposition in corresponding Australian Patent Application Serial No. 736020.
	AM	SUGIYAMA et al., Translation of JP 61-15647 (1986).
	AN	PETERSON et al., "Dietary Constituents Affecting Plasma and Liver Cholesterol in cholesterol-Fed Chicks", Journal of Nutrition, 1953, Vol. 50, Pages 191-201.
	AO	Patent Abstract of Japan, Publication No. 09132512, Published May 20, 1997
	AP	GUNSTONE et al., "Lipids in Foods Chemistry, Biochemistry and Technology", Pergamon Press, New York, pages 147-155.
	AQ	MIETTINEN et al., "Reduction of Serum Cholesterol With Sitostanol-Ester Margarine In A Mildly Hypercholesterolemic Population", The New England Journal of Medicine, Vol. 333, pages 1308-1312, November 1995.
	AR	GYLLING et al., "Serum cholesterol and cholesterol and lipoprotein metabolism in hypercholesterolaemic NIDDM patients before and during sitostanol ester-margarine treatment", Diabetologia, Vol. 37, pages 773-780, 1994.

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 019075-00058	SERIAL NO. Div of 09/713,030
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT MIETTINEN et al.	
		FILING DATE Herewith	GROUP unknown

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO PART.		
	AG	EP 0 898 896 A1	03/1999	EPO					
	AH	0 203 277 A2	12/1986	EPO					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	Appeal against Decision of Opposition Division filed in the EPO on February 21, 2002 including Main Request, Opponent's schematic representation of sitosterol and sitostanol and Proprietor's schematic representation of sitostanol, sitosterol and cholesterol.
	AN	Denke, "Lack of efficacy of low-dose sitostanol therapy as an adjunct to a cholesterol-lowering diet in men with moderate hypercholesterolemia", American Journal of Clinical Nutrition, 1995, vol. 61, pages 392-396.
	AO	Swell et al., "Sterol Specificity of Pancreatic Cholesterol Esterase", Proc. Soc. Exp. Biol. Med., 1954, vol. 87, pages 216-218.
		Vahouny et al., "Absolute Requirement for Free Sterol for Absorption by Rat Intestinal Mucosa", Proc. Soc. Exp. Biol. Med., 1964, vol. 116, pages 496-498.
		Tavani et al., "The sterol substrate specificity of acyl CoA: cholesterol acyltransferase from rat liver", Journal of Lipid Research, 1982, vol. 23, pages 774-781.
		Hendriks, et al., "Spreads enriched with three different levels of vegetable oil sterols and the degree of cholesterol lowering in normocholesterolaemic and mildly hypercholesterolaemic subjects", European Journal of Clinical Nutrition, 1999, vol. 53, pages 319-327.
		Kondo et al., "Isolation of Ovulatory-Active Substances from Crops of Job's Tears", Chem. Pharm. Bull., 1988, vol. 36(8), pages 3147-3152.

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 019075-00058	SERIAL NO. Div. of 09/713,030
LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>		APPLICANT MIETTINEN et al.	
		FILING DATE Herewith	GROUP

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA	5,502,045	3-1996	Miettinen et al.			
	AB	5,958,913	9-1999	Miettinen et al.			
	AC	6,174,560	1-2001	Miettinen et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO PART.		
	AD	EP 0 911 385 A1		EP					
	AE	JP-44-4974	2/28/44	Japan					

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AF	Page 2 of the Written Opinion of WO 92/19640
	AG	Page 2 of the International Preliminary Examination Report of WO 92/19640
	AH	Declaration by Ilkka Etupalta
	AI	<i>Serum Plant Sterols and Cholesterol Precursors Reflect Cholesterol Absorption and Synthesis in Volunteers of a Randomly Selected Male Population</i> , Miettinen et al., Am. J. Epiderm., vol. 131, no. 1:20-31, 1990
	AJ	<i>Fate of Dietary Sterols in Hydrogenated Oils and Fats</i> , P.W. Parodi, J.Am. Oil Chem. Soc., Vol. 52:345-348, 1975
	AK	<i>Saturated Sterols (Stanols) in Unhydrogenated and Hydrogenated Edible Vegetable Oils and in Cereal Lipids</i> , Dutta et al., J. Sci. Food Agric., Vol. 71:383-391, 1996
	AL	<i>Method for Qualitative and Quantitative Determination of Phytosterols in Vegetable Iols by LC-GC off-line</i> , Schuhmann et al., Mitt. Gebiete Lebensm. Hyg., Vol. 87:708-715, 1996
	AM	<i>Sitostanol fatty acid ester content of hydrogenated rapeseed oil</i> , Dr. Dutta's hydrogenation results
	AN	<i>Formation of Sitostanol During Partial and Full Hydrogenation of Vegetable Soybean Oil with Ni-Catalyst</i> , Raisio Benecol Ltd's hydrogenation results

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i>	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 019075-00058	SERIAL NO. Div. of 09/612,198
		APPLICANT MIETTINEN et al.	
		FILING DATE October 14, 2002	GROUP

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AO	<i>Comparison of the effects of plant sterol ester and plant stanol ester-enriched margarines in lowering serum cholesterol concentrations in hypercholesterolaemic subjects on a low-fat diet</i>
	AP	<i>Effects of Low-Fat Yogurt with Plant Stanol Esters and of Consumption Frequency on LDL-Cholesterol Levels, J. Plat et al., Summary of Presentation at 92nd AOCS Annual Meeting and Expo, May 13-16, 2001, Minneapolis, Minnesota, USA</i>
	AQ	Front page of WO 92/19640
	AR	PCT Applicant's Guide (Swedish Patent Office as ISA)
	AS	PCT Applicant's Guide (Swedish Patent Office as IPEA)
	AT	<i>Efficacy of spreads enriched with stanol-stearate esters on blood cholesterol levels, Annex I filed with the Opponent's further submissions of June 27, 2000</i>
	AU	<i>Stanol Components in Edible Fats and Oils, M. Sugano et al., Sci. Byull. Fac. Agr. Kyushu Univ., Vol. 32, no. 1:21-28, 1977</i>
	AV	<i>Ullmann's Encyclopedia of Industrial Chemistry, Vol. A16:152-153</i>
	AW	<i>Elintarvike-tekniikan Perusteet, M. Hiros et al., VAPK-kustannus, Helsinki, 1990, pages 236-241, and translation of passage bridging pages 240-241</i>
	AX	<i>Hydrogenation of sterol esters. Demonstration of hydrogenation of sterol moiety, Annex II filed with the Opponent's further submission of June 27, 2000</i>

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 019075-00058	SERIAL NO. Div. of 09/713,030
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT Miettinen et al.	
		FILING DATE Herewith	GROUP

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AA	Opposition by Unilever N.V. (OPPO 01), European Patent Application No. 91 908 435.0 435.0-2117/594612, September 6, 2002.
AB	RUDD et al., "Pancreatic carboxyl ester lipase (cholesterol esterase)", in Lipases, 1984, pages 185-204 (Ed. Rorgström)
AC	Brockeroff et al, "Cholesterol Esterase", in Lipolytic Enzymes, pages 176-193.
AD	Vanouny et al, "Micellar-Solublized Substrates and Cholesterol Esterase Activity in Vitro", Archives of Biochemistry and Biophysics, 107, 7-15 (1964).
AE	"The effect on cholesterol lowering caused by the difference in fatty acid profile of the stanol ester and control spread", Sept. 6, 2002.
AF	Avart et al, "Substrate Specificity of Neutral Cholesterol Ester Hydrolase", Abstract, June 1985.
AG	D54a, Sitosterol/Sitostanol models, pages 1-12, Sept. 6, 2002.
AH	D49, b-sitosterol, Reference list for stanols, September 6, 2002.
AI	Department of Health and Human Services, "Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease; Interim Final Rule", Federal Register, Vol. 65, No. 175, September 2000.

EXAMINER	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	